Application no.: 10/020,531 Docket no.: GTI-1180-CT

REMARKS

Applicants carefully reviewed the outstanding non-final Office action and provide the remarks hereafter. No claim amendments are presented at this time. The Office sustained the rejection of the pending claims for alleged anticipation and obviousness in view of a single document, Leone *et al.* (U.S. Pat. No. 5,505,700, hereafter referred to as "Leone"). The claims are not rejected on any other grounds.

In their previous submission on 16 August 2004, Applicants interpreted Leone as not disclosing, teaching or suggesting the claimed subject matter, which is directed to a catheter having a first and second electrode on the catheter surface. Applicants and the Office each noted that Leone consistently refers to an "internal" electrode on the catheters and does not specifically define the term "internal." Applicants and the Office disagree as to the orientation of the "internal" electrode in the catheters disclosed in Leone. Applicants interpret the "internal" electrode as not oriented on the catheter surface based upon the drawings and disclosure of Leone. The Office has submitted an alternative interpretation that the "internal" electrode is located on the catheter surface. After considering the Office action, Applicants maintain their previous interpretations of the cited document and traverse the remaining rejections.

The Pending Claims are Novel and Not Anticipated Over Leone

Prima facie anticipation is established only when the cited document provides an enabling disclosure and describes, either explicitly or inherently, all of the elements of the rejected claim(s). Independent claims 1 and 17 specify that the first and second electrodes are on the exterior surface of the catheter (e.g., specification on page 13, paragraphs 0038 and 0039 and Figure 1). Leone fails to anticipate any of the pending claims because it requires that one of the catheter electrodes is an internal electrode.

While not specifically defined, Leone repeatedly refers to one of the electrodes in the disclosed catheters as an "internal" electrode. For example, the specification at column 2, lines 47-53, broadly refers to the invention as a catheter comprising one or more balloons, an internal electrode, and an integral electrode, and the claims are consistent with this characterization.

There are interpretations of the term "internal" that can be dismissed. First, the term "internal" does not refer to the position of the electrode with respect to balloon orientation, as some embodiments include only one balloon. Second, the Office and Applicants noted that Leone refers to prior art catheters having an electrode "external" to the subject's body (column 2, lines 5-23 in Leone). This reference to an "external" electrode in Leone does not itself define the position of the "internal" electrode in the catheter, nor does it suggest that the "internal" electrode is on the catheter surface. Rather, the drawings and disclosure of Leone define catheters having an "internal" electrode not located on the catheter surface, as explained hereafter.

Leone consistently refers to the "internal" electrode as not located on the exterior surface of the catheter. For example, Figure 3 and the specification at column 5, lines 41-42 of the cited patent discuss a catheter embodiment in which a porous membrane covers the internal electrode. In this embodiment, the electrode clearly is not on the exterior surface of the catheter assembly because it is located beneath the membrane layer. Also, Leone at column 6, lines 27-28, refers to the integral electrode 66 in Figure 4 as "external," which by inference precludes the internal electrode from being on the catheter exterior. The Office has not countered this position according to Applicants' assessment of the outstanding Office action.

This use of the term "internal" is consistent with an interpretation that the electrode 35 in Figure 2 is <u>not</u> on the exterior surface of the catheter assembly. The shaded rendition of catheter treatment length 34 does not represent porous or osmotic passageways because the description at column 4, lines 51-57, makes it clear that the catheter contains <u>either</u> ports 19 <u>or</u> pores <u>or</u> osmotic passageways. According to this language in the cited document, Figure 2 depicts the catheter configuration with ports 19 only, with the shaded rendition of treatment length 34 thus representing a structural feature other than pores or osmotic passageways. Applicants noted in the previous amendment that the shaded rendition of catheter treatment length 34 is consistent with drawing conventions in which elevations within a structure are distinguished by shading, in accordance with MPEP 608.02 IX. The Office countered this interpretation, on page 7 of outstanding Office action:

> This disclosure does not mean that the catheter has either ports or pores or osmotic passageways, but not a combination. For example, if a catheter has

> ports and pores, then a certain amount of fluid will flow out of the ports and pores, but fluid in general will flow out of both. Moreover, it appears that the shaded region of the catheter treatment length (34) in Figure 2 for example is a means to indicate what portion of the catheter is the catheter treatment length (34), rather than to indicate that the inside of the catheter is being shown.

Applicants do not understanding this interpretation and request further explanation. Leone uses the language "either" and "or," indicating that one of ports, pores or osmotic passageways are incorporated into a catheter to effect transmission of fluids from the catheter. Figure 2 shows an embodiment with ports, and due to the language in the specification, the catheter would not include pores or osmotic passageways. Thus, this language in the specification is not consistent with the shading being representative of pores or osmotic passageways since ports 19 are shown in Figure 2.

Also, it is not understood why the Office interprets the shading in Figure 2 as depicting treatment length 34, as Applicants find no evidence in Leone that suggests this interpretation. Applicants do not see a reason why Leone would shade treatment length 34 since other components of the catheter, such as the electrode 35, are readily visualized without shading. For example, electrode 35 in Figure 1 is readily visualized without the treatment length being shaded. Thus, Applicants do not understand why the Office has countered an interpretation that the shading in Figure 2 is representative of a different elevation and not the surface of the catheter.

As further evidence of this interpretation, Applicants previously noted that the stated use of the internal electrode for driving iontophoresis is further evidence that the internal electrode in Figure 2 is not on the exterior catheter surface. For example, the specification states at column 5, lines 23-27:

> Voltage is applied, and the resulting charge on the internal electrode is the same as that on the medicament or medicament carrier, thereby providing the impetus for the medicament to move away from the internal electrode and to and/or into the vessel wall.

An internal electrode located on the catheter surface and having the same charge as the medicament or medicament carrier would likely provide impetus for the medicament to move towards the catheter interior. An internal electrode located within the catheter would provide

more of an impetus for pushing the medicament away from the catheter. The Office did not address this point in the previous amendment according to Applicants' assessment of the outstanding Office action.

The Office stated on page 8 of the outstanding action that it is not clear why Figure 2 should be interpreted as not illustrating a porous membrane component present on the catheter based upon the meaning of "iontophoresis." Applicants provide the following analysis to support this interpretation of Figure 2. Leone summarizes the invention as an "electroosmotic infusion" catheter for delivery of medicaments or treatment fluids to a location within a living body (column 2, lines 40-41). The Office previously equated this delivery method to "iontophoresis" (paper 19, page 6). Applicants noted in the previous amendment that the meanings of the terms "electroosmotic infusion" and "iontophoresis" involve the passage of molecules through a semi-permeable barrier. For example, Leone specifies at column 1, lines 64-66 that iontophoresis technology "uses an electrical potential or current across a semi-permeable barrier to drive ionic medicaments toward the target treatment site (emphasis added)." Also, "electroosmosis" is defined as "the diffusion of a substance through a membrane in an electric field (emphasis added)" by a scientific dictionary (e.g., http address cancerweb.ncl.ac.uk). Because these meanings make it clear that iontophoresis and electroosmosis involve movement of molecules across a semi-permeable barrier, Applicants maintain that Figure 2 can be interpreted as showing the interior surface of the catheter treatment length 34 without the semi-permeable barrier requisite for electroosmotic infusion.

Thus, the drawings and the specification of Leone consistently refer to an "internal electrode" as an electrode not located on the exterior surface of the catheter. For these reasons, Applicants respectfully request that the Office withdraw the rejection under 35 U.S.C. § 102(b).

The Pending Claims are Inventive and Not Obvious over Leone

Applicants also traverse the alleged obviousness of claims 29-34 in view of Leone. Claimed matter is *prima facie* obvious only when the cited document or combination of documents teaches or suggests all of the claimed elements, the person of ordinary skill in the art was motivated to modify the document(s) as suggested in the Office action, and there was a reasonable expectation of success. *See* MPEP 2142, *et seq.*

As described above, the claimed catheters, which include electrodes located on the exterior surface of a portion of the catheter body, differ from the catheters disclosed in Leone because the latter require an internal electrode. Modifying an internal electrode in catheters of Leone to an external electrode is not an obvious selection, and therefore Leone does not teach or suggest such a modification. Leone states the internal electrode is useful for driving medicament away from the catheter towards the vessel wall by electroosmotic infusion (e.g., column 5, lines 22-27). Because the cited patent discloses placement of one electrode internally within the catheter to push the medicament away from the catheter, the ordinarily skilled artisan would find no reason to shift the placement of the electrode to the exterior surface of the catheter. Such a shift might result in a catheter that does not effectively work for its intended purpose of repelling medicament from the catheter.

Leone also suggests that the disclosed catheters are useful for "electroporation" (column 7, lines 39-43), as that term is unconventionally defined, i.e., as "the electrical breakdown of cells which contain substances such as hemolytic compounds, genes, and the like." Id. Accordingly, there was no motivation for a person of ordinary skill in the art to modify the internal electrode configuration for the purpose of conducting electroporation procedures as taught by Applicants since the cited patent reported that goal already was accomplished.

Because Leone does not teach or suggest modifying the internal electrode configuration to provide an exterior electrode configuration, and because there was no motivation for the person of ordinary skill in the art to make such a modification, the claimed subject matter is not obvious. Accordingly, Applicants respectfully request that the Office withdraw the rejection of the pending claims under 35 U.S.C. § 103(a).

CONCLUSIONS

Applicants respectfully submit that, after entry of the amendment above, all pending claims will be in condition for allowance, and they earnestly solicit an early notice to such effect. That said, should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at (858) 623-9470 so that they may be promptly resolved.

Application no.: 10/020,531 Docket no.: GTI-1180-CT

In the unlikely event the transmittal letter is separated from this document and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to the credit card disclosed in form PTO-2038 filed with this document.

Respectfully submitted,

Dated: 28 MARCH 2005 By: _____

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